December 11, 2000

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir or Madam:

Re: Docket No. 98N-0331: Draft Guidance for Staff, Industry and Third Parties Implementation of Third Party Programs Under the FDA Modernization Act of 1997

The Orthopaedic Surgical Manufacturers Association (OSMA) is a trade association whose membership consists of manufacturers of orthopaedic surgical appliances, implants, instruments and equipment. The majority of our companies manufacture temporary internal fixation devices, including bone plates, bone screws, pins, wires and rods, the subject of these comments.

We are taking the opportunity to respond, although the time period for comments may have elapsed. In our opinion, it is vital that we share our thoughts which essentially reiterate those submitted by AdvaMed on August 28, 2000.

OSMA, like AdvaMed, commends the agency for taking steps to expand the list of Class II devices eligible for third party review except those that are prohibited under Section 210 of the Food and Drug Administration Modernization Act of 1997. FDAMA, of course, specifies that an accredited person may not review any Class III device or any Class II device that is permanently implantable, life-supporting, life sustaining, or for which clinical data are required.

As an industry trade association, we take exception to including intramedullary fixation rods, bone plates, nail/plate combinations, bone screws, nuts, washers, intramedulary nails, bone pins and wires under the "permanently implantable" definition. These devices are defined in CFR 888.3020, 888.3030, and 888.3040. All orthopaedic device manufacturers consider these products to be temporary internal fixation devices and recommend removal when the fracture has healed. The devices serve little or no purpose after bone consolidation occurs. Moreover, fracture fixation devices have an extremely long history of safe and effective use. Bone plates, for example, have been used clinically for more than ninety years. Indications for use and the associated risks for fracture fixation devices are well established and commonly known.

We refer you to 21 CFR 821, the regulations pertaining to Medical Device Tracking. Under the definitions section [821.3 (f)], a *permanently implantable device* means a device that is intended to be placed into a surgically or naturally formed cavity of the human body to continuously assist, restore, or replace the function of an organ system or structure of the human body throughout the useful life of the device. *The term does not include any device which is intended and used for temporary purposes or which is intended for explantation.* Based on this definition and standard labeling practices in our industry, the devices mentioned above are certainly not considered permanently implantable.

ORTHOPEDIC SURGICAL MANUFACTURERS ASSOCIATION
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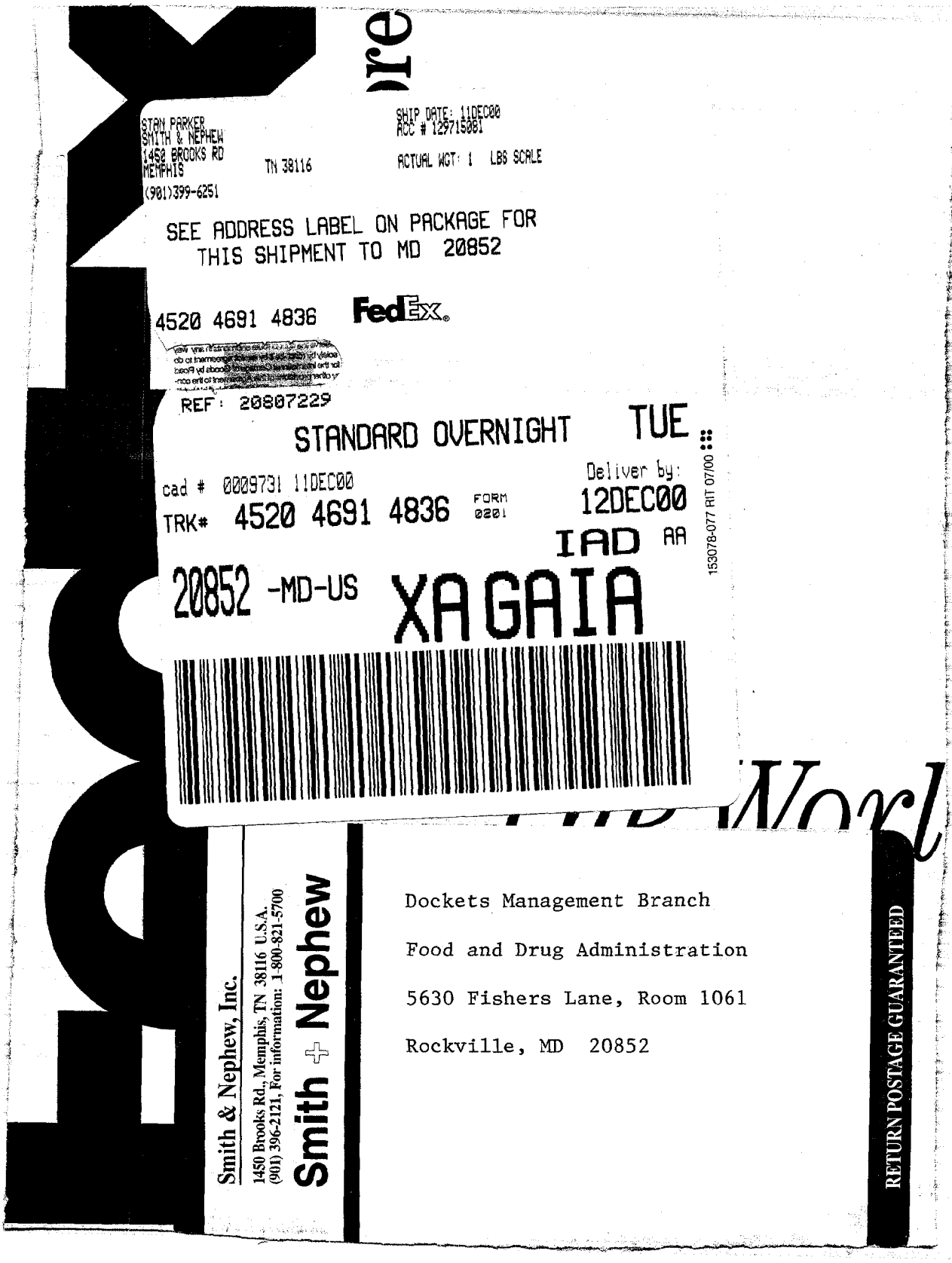
We suggest that a permanently implantable device be defined as a device which is to be implanted in human body for more than one year. Further, that the trauma devices mentioned be eligible for the pilot program for third party review.

Please accept our comments as part of your deliberation and include temporary implantable orthopaedic devices to the proposed expansion list.

Sincerely,

OSMA

Tom Craig
President



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